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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,492	07/15/2002	Moulay A. Alaoui-Jamali	SWA-002US	3246
32254	7590	09/28/2004	EXAMINER	
KEOWN & ASSOCIATES 500 WEST CUMMINGS PARK SUITE 1200 WOBURN, MA 01801			FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/069,492

Applicant(s)

ALAOUI-JAMALI ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on June 21, 2004.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Claim 3 is incomplete because it lacks a subject to which the claim-designated composition is administered. The lack of clarity renders the claim vague and indefinite.

Claim Rejections - 35 USC § 102

Claims 1-5 as amended remain/are/is rejected under 35 U.S.C. 102(b) as being anticipated by Ishii et al. (C2, JP 62081349 A), Tozyo et al. (C3, Chemical Pharmaceutical Bulletin, 1994, 42: 1096-1100.) and Ishii et al. (N, JP 62081379). The rejection stands for the reasons set forth in the previous Office action and for

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the reasons set forth below. Newly applied to Claim 3 as necessitated by amendment.

Applicant claims a biologically active agent extract isolated from *Achillea millefolium* dried plant, said extract having an anti-tumorogenic and anti-metastatic activity. Applicant further claims an extract according to claim 1, said extract consisting of crude methanol extract. Applicant claims a method for treating malignant tumor and/or metastases thereof, said method comprising administering a therapeutically effective amount of a biologically active extract isolated from *Achillea millefolium* having anti-tumorogenic and anti-metastatic activity. Applicant claims an anti-tumorogenic and anti-metastatic composition to treat a malignant tumor and/or metastases thereof, said composition comprising a therapeutically effective of an extract isolated from *Achillea millefolium* dried plant having antineoplastic activity, and a suitable carrier. Applicant claims a method for treating a malignant tumor and/or metastases thereof in a patient, said method comprising administering to said patient a therapeutically effective amount of a biologically active extract isolated from *Achillea millefolium* with a pharmaceutically acceptable carrier.

Applicant argues that neither Ishii (C2, JP 62081349 A) nor Tozyo anticipate the claimed subject matter because, "Ishii et al. and Tozyo et al. do not teach an extract from the *Achillea millefolium* whole dried plant having an anti-tumorogenic and anti-metastatic activity." However, Applicant's argument is neither persuasive nor commensurate in scope to the limitations of the claimed invention because both Ishii (JP '349) and Tozyo teach a methanolic extract

obtained from dried plant material of *Achillea millefolium* having anti-tumor activity. While Applicant appears to argue the criticality for an extract obtained from the whole dried plant of *Achillea millefolium*, the Office notes that the claims merely recite "dried plant" versus "whole dried plant". Given the broadest breadth of interpretation of the claims, the phrase "*Achillea millefolium* dried plant" is read as any and all dried plant parts or materials obtained from the claim-designated plant. Moreover, each of Ishii (JP '349) and Tozyo teach a method for treating leukemia in mice transplanted with P388 leukemia comprising administering therapeutic amounts of the anti-tumor agent to mice, wherein the administration of therapeutically effective amounts of the composition increased the life span of the mice. Neither Ishii nor Tozyo expressly teach that the reference extracts have anti-metastatic activity and antineoplastic activity, *per se*. However, the claimed functional properties are inherent to the compositions taught by Ishii and Tozyo because the ingredients and the extraction solvent are one and the same as disclosed in the instantly claimed invention of Applicant. Thus, a biologically active extract isolated from dried plant material of *Achillea millefolium* having anti-tumorogenic, anti- anti-metastatic activity and antineoplastic activity is inherent to the compositions taught by Ishii and Tozyo.

On page 5 of Applicant's "REMARKS" under "Rejection of Claims 3 and 5 Under 35 U.S.C. §102(b)", Applicant directs the arguments to Claims 3 and 5. However, Claims 1, 2, 4 and 5 were rejected under 35 U.S.C. 102(b) as being anticipated by Ishii (N, JP 62081379) as set forth in the previous Office action dated March 19, 2004, on page 11. Applicant's main argument is directed to the

idea that the leukemia models used by Ishii and Tozyo to demonstrate the anti-tumor activity of the reference biologically active plant extract are not as new or relevant as the solid tumor model used in the testing of the biologically active plant extract disclosed by Applicant. However, Applicant's arguments are neither persuasive nor commensurate in scope to the limitations of the claimed subject matter. Firstly, Ishii (N, JP '379) teaches an anti-tumor agent isolated from *Achillea millefolium*. For example, a crude extract was extracted with methanol from the dried flowers of *Achillea millefolium* and subsequently purified twice by silica gel chromatography. Ishii further teaches a method for treating leukemia in mice transplanted with P388 leukemia comprising administering therapeutic amounts of the anti-tumor agent to mice, wherein the administration of therapeutically effective amounts of the composition increased the life span of mice with transplanted P388 leukemia by 38% and 48%. Secondly, Tozyo expressly teaches evaluating the anti-tumor activity of a methanolic extract of *Achillea millefolium* by the increase in life span of mice bearing leukemia after receiving therapeutically effective amounts of the reference extract.

Each of the references of Ishii (JP '349 and JP '379) and Tozyo anticipate the claimed subject matter.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood.

**MICHELE FLOOD
PATENT EXAMINER**

MCF

September 27, 2004